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| EXAMINER |
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GWARTNEY, ELIZABETH A

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| ART UNIT | PAPER NUMBER |
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1794

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03/31/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. 10/576,813 | Applicant(s) STIEFEL, THOMAS | |
| | Examiner ELIZABETH GWARTNEY | Art Unit 1794 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 16, 17 and 19-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 16-17 and 19-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Amendment filed December 28, 2009 has been entered. Claim 18 has been cancelled and claim 23 has been added. Claims 1-8, 16-17 and 19-23 are pending.
2. The previous claim objections and 112, 2nd Paragraph rejections have been withdrawn in light of applicant's amendments made December 28, 2009.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 23 recites “wherein the composition comprises electrolytes exclusively” in lines 1-

2. While there is support in the present specification nutrition trace element compositions *containing electrolyte concentrates* exclusively, there is no support for a nutrition trace element composition that *comprises electrolytes exclusively*. It is the Examiner's position that a composition *comprising electrolytes* exclusively is different than a composition *containing electrolyte concentrates* exclusively.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claim 1-6, 16 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frankel ("Supplementation of Trace Elements in Parenteral Nutrition: Rationale and Recommendations").

Regarding claims 1 and 4, Frankel discloses a total parenteral nutrition composition supplemented with trace elements including *a minimum provision* of 50 meg/day (i.e. 0.05 mg/day) of selenium and 10 mg/day of zinc (p. 587/ paragraph 4, p. 588/paragraph 6). Frankel discloses that the parental administration of iron is problematic and does not indicate

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supplementation of iron in total parenteral nutrition compositions (p.583/paragraph 3, p. 589/paragraphs 4-5).

Given Frankel discloses total parenteral nutrition composition supplemented with selenium and zinc in quantities that overlap with those presently claimed, it would have been obvious to one of ordinary skill in the art at the time of invention to have selected the overlapping portion of the ranges disclosed by the reference because overlapping ranges have been held to be a prima facie case of obviousness. *In re Malagari*, 182 USPQ 549.

Regarding claims 2-3 and 5, Frankel discloses all of the claim limitations as set forth above. Given Frankel discloses a parenteral composition, it is clear that the composition is inherently an infusion solution that exists as an aqueous solution and is suitable for parenteral administration.

Regarding claim 6, Frankel discloses all of the claim limitations as set forth above. Frankel also discloses total parenteral nutrition compositions comprising chromium and copper (p. 583/paragraphs 3-5, p. 584/paragraphs 1-9, p.585/paragraphs 1-4).

Regarding claims 16 and 19, Frankel discloses administering a total parenteral nutrition composition supplemented with a ***minimum provision*** of 50 meg/day (i.e. 0.05 mg/day) of selenium and 10 mg/day of zinc to a human (p. 587/ paragraph 4, p. 588/paragraph 6). Frankel discloses that the parental administration of iron is problematic and does not indicate supplementation of iron in total parenteral nutrition compositions (p.583/paragraph 3, p. 589/paragraphs 4-5).

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Regarding claim 20, Frankel discloses all of the claim limitations as set forth above.

Frankel also discloses administering a total parenteral nutrition composition further comprising chromium and/or copper (p. 583/paragraphs 3-5, p. 584/paragraphs 1-9, p.585/paragraphs 1-4).

Regarding claims 21-22, Frankel discloses all of the claim limitations as set forth above.

Further, Frankel discloses that in some cases selenium supplemented compositions have been administered daily for 3-4 months (p.587/paragraph 5). Frankel also discloses that zinc supplemented compositions have been administered daily for 92 months (p.588/paragraph 6).

Regarding claim 23, Frankel discloses all of the claim limitations as set forth above.

Given Frankel disclose a supplement comprising chromium, copper, manganese, selenium and zinc, it is clear that the composition would intrinsically comprise electrolytes exclusively.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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11. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frankel (“Supplementation of Trace Elements in Parenteral Nutrition: Rationale and Recommendations”).

Regarding claims 7-8, Frankel disclose all of the claim limitations as set forth above. While Frankel disclose a total parenteral nutrition composition containing selenium and zinc, the reference does not explicitly disclose that composition is formulated as a 10 ml infusion solution that exists as an aqueous solution in an ampoule.

It is well known to package parenteral compositions in parenteral containers, including an ampoule, vial or bag. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have packaged the total parenteral nutrition composition of Frankel in any parenteral container, including an ampoule, and arrived at the current invention.

Further, it would have been obvious to one of ordinary skill in the art to have formulated the total parenteral nutrition composition in any size of dose, including 10-ml, because change in size is not patently distinct over the prior art absent persuasive evidence that the particular configuration of the claimed invention is significant. See *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955); *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). MPEP 2144.04[R-1].

12. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frankel (“Supplementation of Trace Elements in Parenteral Nutrition: Rationale and Recommendations”) in view of Ballevre et al. (US 2003/0161863).

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Regarding claim 17, Frankel discloses all of the claim limitations as set forth above. While Frankel disclose administering a total parenteral nutrition composition comprising selenium and zinc to a human, the reference does not explicitly disclose that the human is an intensive care patient or a sepsis patient.

Balleve et al. teach an enteral nutrition composition comprising about 40 to about 100 µg /dose of selenium and 5 to 10 mg/dose of zinc (Abstract, [0029]-[0030]) that is administered to critically ill patients including those with sepsis ([0005], [0011]). Further, Balleve et al. discloses an enteral nutrition composition that does not comprise iron (*see* Example 1-[0048]-[0050]).

Given that Balleve et al. teach that is was known to administer nutritional compositions comprising selenium and zinc to critically ill patients including those with sepsis, since Balleve et al. teach a composition substantially similar l to that of Frankel and that presently claimed, it would have been obvious to one of ordinary skill in the art to have administered the total parenteral nutrition composition of Frankel to critically ill patients including those with sepsis.

Response to Arguments

13. Applicant's arguments with respect to claims 1-6, 16 and 18-22 under 35 USC §102(a) in have been considered but are moot in view of the new ground(s) of rejection.

The previous rejections under 35 USC §102(a) have been withdrawn in light of applicant's amendments made December 28, 2009. However, based on applicant's amendment, claims 1-6, 16 and 19-23 are now rejected under 35 USC §103(a) in view of Frankel ("Supplementation of Trace Elements in Parenteral Nutrition: Rationale and Recommendations").

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Applicant alleges unexpected results based on evidence presented in a Declaration under 37 C.F.R. §1.132 of Dr. Thomas Stiefel. The question as to whether unexpected advantage has been demonstrated is a factual question. *In re Johnson*, 747 F.2d 1456, 1460, 223 USPQ 1260, 1263 (Fed. Cir. 1984). Thus, it is incumbent upon applicant to supply the factual basis to rebut the prima facie case of obviousness established by examiner. See, e.g., *In re Klosak*, 455 F.2d 1077, 1080, 173 USPQ 14, 16 (CCPA 1972).

Applicant, however, does not provide an adequate explanation regarding any factual showing in the Declaration of unexpected results as the samples have not been shown to be commensurate in scope with rejected claims. For example, the rejected claims are not limited to the compositions set forth in the Syntrace® product. The Syntrace® product is limited to a composition comprising 1 mg of selenium and 30 mg of zinc per dose while the claims encompass composition comprising from 0.5 mg to 2 mg selenium and from 10 mg to 100 mg zinc per dose. Nor have the applicants shown that comparison samples in said examples fairly represent the closest prior art. It is well established that the evidence of unobviousness must be commensurate in scope with the claimed subject matter. See *In re Kerkhoven*, 626 F.2d 846, 851, 205 USPQ 1069, 1072-73 (CCPA 1980) and *In re Clemens*, 622 F.2d 1029, 1035, 206 USPQ 289, 896 (CCPA 1980). Moreover, given the prior art teachings, the applicants have not met the burden of establishing that the reported results would have been truly unexpected to a person of ordinary skill in the art on this record or otherwise established the unobviousness of the claimed composition. *In re Klosak*, 455 F.2d 1077, 1080, 173 USPQ 14, 16 (CCPA 1972).

In addition, while applicant has established that normal levels of selenium were achieved in the blood and serum of patient after administration of a composition comprising more

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selenium than a composition which did not produce normal levels of selenium, a person of ordinary skill in the art would not find these results unexpected. One of ordinary skill in the art would expect that the greater the dose the faster normal levels of selenium in the blood and serum would be achieved.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH GWARTNEY whose telephone number is (571)270-3874. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./

Examiner, Art Unit 1794

/Keith D. Hendricks/

Supervisory Patent Examiner, Art Unit 1794